

REMARKS

The Final Office Action mailed April 9, 2010 presents the examination of claims 1-9, 11, 13-15, 17 and 18. Claim 19 was added by an Amendment filed July 9, 2010 that was entered, but did not place the claims into condition for allowance.

Claims 1-7, directed to withdrawn subject matter, are canceled herein. Applicants reserve the right to file an application directed to the canceled subject matter pursuant to 35 USC § 120.

Claims 8 and 19 are amended to recite a method for localizing mesenchymal stem cells to an injury site. Support for this amendment is found in the specification at least at paragraph [0007] of the specification.

Claims 8 and 19 are amended to recite more particularly the specific growth factors recited, that is, to define the subtypes of some of them. Support for these amendments is found in the specification at least at paragraph [0047].

Claims 20 and 21 are newly added. Support for new claims 20 and 21 is provided by the specification at least at paragraph [0033] taken with paragraph [0030] and Example 4 - paragraph [0059].

Claims 22-28 are also newly added, which recite the particular growth factor used in working Example 4.

No new matter is added to the application by any amendment and no new issue for consideration by the Examiner is raised by any amendment.

Rejections Under 35 USC § 112, 1st Paragraph

Claims 8, 9, 11, 13-15, 17 and 18 are rejected under 35 USC § 112, first paragraph, for alleged lack of enablement by the specification. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

As discussed in the interview of August 12, 2010, the Examiner's greatest concern with respect to enablement is that the claims recite(d) a method for regeneration therapy, but there is no evidence in the specification that regeneration actually occurs. The Examiner did agree that the data of record show that the claimed method could indeed localize mesenchymal stem cells

to an injury site, and so the claims have been amended to recite a method of localizing mesenchymal stem cells to an injury site as suggested by the Examiner.

The Examiner also explained in the interview of August 12 that there is no working example providing *in vivo* results other than for use of the growth factor PDGF-BB. Applicants submit that submission of *in vivo* results is not required to establish enablement of a therapeutic method. *In vitro* results are sufficient, so long as there is a reasonable correlation between the *in vitro* experiments and the nature of the therapy claimed. *See, e.g., Cross et al. v. Iizuka et al.*, 224 USPQ 739 (Fed. Cir. 1985).

In the present instance, the therapeutic method claimed relates to homing of mesenchymal stem cells. The specification provides *in vitro* testing results showing that the growth factors listed in the claims have chemoattractant activity for mesenchymal stem cells derived from different tissues (bone marrow and ilium - *see Example 2*). Thus, the *in vitro* tests show a reasonable relationship to the claimed therapy.

Furthermore, the specification shows that the *in vitro* tests of Examples 2 and 3 are predictive of results *in vivo*; PDGF-BB is among the growth factors shown to be effective in the *in vitro* experiments, and Example 4 of the specification demonstrates that PDGF-BB is effective *in vivo*.

For all of the reasons set forth above, and those explained in the Amendment of July 9, 2010, Applicants submit that the full scope of claims 8, 9, 11, 13-15 and 17-28 is enabled by the specification. Accordingly, the instant rejection should be withdrawn.

Applicant believes the pending application is in condition for allowance. Such favorable action is respectfully requested.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Susan W. Gorman, Ph.D., Reg. No. 47,604, at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

Dated: September 8, 2010

Respectfully submitted,

By Gerald M. Murphy, Jr.
Gerald M. Murphy, Jr.
Registration No. 28,977
BIRCH, STEWART, KOLASCH & BIRCH, LLP
8110 Gatehouse Road, Suite 100 East
P. O. Box 747
Falls Church, Virginia 22040-0747
(858) 792-8855
Attorneys for Applicants